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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,287	06/26/2001	Jennifer L. Hillman	PF-0334-2 DIV	2779
27904	7590	06/30/2004	EXAMINER	
INCYTE CORPORATION EXPERIMENTAL STATION ROUTE 141 & HENRY CLAY ROAD BLDG. E336 WILMINGTON, DE 19880			NOLAN, PATRICK J	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/892,287

Applicant(s)

HILLMAN ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 30-45 is/are pending in the application.
- 4a) Of the above claim(s) 30,33,35 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 39 is/are allowed.
- 6) ☒ Claim(s) 11,31,32,34,37,38 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Applicant's amendments, filed 3/24/03, 6/6/03 and 1/29/04 are acknowledged. Claims 1-10, 12-29 and 46-47 have been cancelled previously. Claims 11 and 30-45 are pending.
2. Claims 30, 33, 35 and 44-45 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 7.
3. In view of the rejections set forth below, the issue of rejoinder of claims 30, 33, 35 and 44-45 is held in abeyance.
4. Claims 30, 33, 35 and 44-45 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 11, 31-32, 34 and 36-43 are under consideration in the instant application.

Claim Rejections – 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 37-38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Laxminarayan et al. (J. Biol. Chem. 1993; 268:4968-4974, of record) in view of GenBank Accession #AAB03214 (Nussbaum, R.L., (GI 1399101, GenBank Sequence Database, Accession No. AAB03214, National Center for Biotechnology Information, National Library of Medicine, Bethesda, MD 20894, Release Date 29 June 1996, Version AAB03214.1, of record), as evidenced by the alignment previously provided, for reasons set forth in the Paper mailed 8-26-03.

7. Claims 40-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (J. Biol. Chem. 1994; 269(5):3403-3410, of record) in view of GenBank Accession #AAB03214 (Nussbaum, R.L., (GI 1399101, GenBank Sequence Database, Accession No. AAB03214, National Center for Biotechnology Information, National Library of Medicine, Bethesda, MD 20894, Release Date 29 June 1996, Version AAB03214.1, of record), as evidenced by the previously provided alignment, for reasons of record set forth in the Paper mailed 8-26-03.

8. Claims 11, 31-32, 34 and 42-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer et al. (J. Biol. Chem. 1994; 269(5):3403-3410, of record) in view of GenBank Accession #AAB03214 (Nussbaum, R.L., (GI 1399101, GenBank Sequence Database, Accession No. AAB03214, National Center for Biotechnology Information, National Library of Medicine, Bethesda, MD 20894, Release Date 29 June 1996, Version AAB03214.1, of record), as evidenced by the alignment provided previously, and as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886), and further in view of Ramakrishnan et al. (US Pat. No. 5,817,310, of record), for reasons set forth in the Paper mailed 8-26-03.

Applicant's arguments filed 1-29-04 have been fully considered but are not found persuasive.

Applicant's arguments against the 35 USC 103 rejections are based primarily on two positions.

1. The phrase specifically binds excludes antibodies made to other protein that would also bind applicants claimed protein.

2. That the prior art EST amino acid sequence is not 90% identical to applicant's claimed SEQ ID NO. 1 and so the prior references cannot make obvious applicant's claimed invention.

In response to Applicant's first point, when one of skill considers the scope of a claimed term or phrase one must look to the specification for a clear definition of the term or one of skill is required to apply what is an art recognized definition for the term in understanding the scope of the claim. Applicant has pointed to parts of the specification for clear limiting definition of the term "specifically binds". The Examiner has reviewed said passages and finds no direct support for a phrase of specifically binds that limits the antibodies being generate to only bind to the claimed protein. In other words that no specific cross reactive binding is included in the genus of antibodies claimed.

Applicant is guided to Kuby et al., attached, which defines the term cross reactivity as a property of antibodies to specifically bind two antigens that share identical epitopes. Since Applicant has provided direct evidence that the prior art protein, Nussbaum et al., and the SEQ ID NO. 1 share multiple identical epitopes, the antibodies to the Nussbaum et al., protein would be expected to cross react and therefore specifically bind applicant's claimed protein. Applicant's included Dictionary reference to specificity is not found persuasive since it is not what one of skill in the art would consider the most closely related "Dictionary reference". A textbook in Immunology is substantially more relevant.

In response to Applicant's second point. The claims being rejected are product claims, the immunogen being used to generate the antibodies is irrelevant as long as the product taught by the prior has all of the functional and structural properties of the claimed product.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Claims 36 and 39 as currently recited are allowable.

11. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.



Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

June 24, 2004